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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-13-13AGH]
Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly S. Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Examining Traumatic Brain Injury in Youth - NEW - National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Traumatic brain injury (TBI) is one of the highest priorities in public health because of its magnitude, economic and human impact, and preventability. The Centers for Disease Control and Prevention (CDC) estimates that approximately 1.7 million TBIs are sustained in the United States annually, either alone or in conjunction with another injury or condition. These figures may be an underestimation as they do not include people who are treated in physicians' offices or outpatient facilities, those who did not seek medical care, military personnel, or Americans living abroad. Moreover, the number of sports and recreation-related TBIs treated in U.S. emergency departments is increasing and has increased steadily since the early 2000s. Children, ages 0 to 4 years and adolescents, ages 15-19, are at the greatest risk of sustaining a TBI. A TBI is caused by a bump, blow or

jolt to the head or a penetrating head injury that disrupts the normal function of the brain. The severity of a TBI may range from "mild" (a brief change in mental status or consciousness) to "severe" (an extended period of unconsciousness or amnesia after the injury).

In 1996, Congress passed Public Law 104-166, the Traumatic Brain Injury Act, which charged CDC with implementing projects to reduce the incidence of traumatic brain injury. The CDC definition of TBI uses selected codes of the International Classification of Diseases, 9th Clinical Modification (ICD-9 CM) to identify cases of TBI from hospital and non-hospital databases containing billing records for services rendered to patients. It is thought, however, that the ICD-9 CM codes currently used in CDC's surveillance system to capture cases of TBI are not sufficiently sensitive to capture diagnosed TBI. CDC, therefore, would like to collect de-identified medical information of a representative sample of pediatric patients, from two clinical settings, who received a confirmed diagnosis of mild to severe TBI and link these patients to their administrative medical claims forms. Collectively, the data will allow CDC to estimate the sensitivity of currently utilized ICD-9 CM codes to capture cases of diagnosed TBI, as well as ICD-9 CM codes not currently being utilized that may improve the

sensitivity to capture cases of TBI. We propose to conduct a retrospective cross-sectional study of a random sample of patients with a suspected TBI within two clinical settings (Emergency Departments and Concussion Clinics).

Information for this study is being collected to better understand the coding practices related to TBI among children within multiple clinical settings. The data will benefit public health by providing a more accurate case definition of TBI for the Central Nervous System (CNS) Injury Surveillance. Results from this study will be shared with CDC stakeholders, such as state and local health departments, clinicians and TBI-related medical researchers through CDC reports and peer-reviewed publications.

CDC requests OMB approval for three years to abstract data from medical and billing records dated April 1st to September 30, 2013. Data will be collected electronically, analyzed with findings compiled in a final report. The following information is needed from the medical record: Age at injury, encrypted or randomly generated identification number (that can be linked to billing system), head injury assessment value (indicator variable, Yes/No), Traumatic injury mechanism, Glasgow Coma Scale (GCS) score, ICD-9 CM codes and External cause of injury (E) codes if available, Head injury assessment value

(indicator), Confirmed Diagnosis of TBI (Yes/No), based on the TBI case definition and if yes, Injury Type. The necessary data fields from the hospital billing system are: Encrypted or randomly generated identification number (that can be linked to medical chart), diagnosis codes (all available fields for ICD-9-CM, E and V-codes), procedural codes (all available fields for ICD-9 CM, CPT-4) From the abstracted medical chart data contained in the TBI Data Abstraction Tool, a frequency of all observed ICD-9 CM codes will be created. Calculations of frequencies and code sensitivity of the ICD-9 CM codes will be calculated to develop recommendations for specific ICD-9 CM in the CDC IDC-9 Code definition.

The TBI Data Abstraction tool will be used to create the final analytic dataset for the 'Examining Traumatic Brain Injury in Youth' project. Data will be abstracted into the dataset in two separate phases during the study. During the first phase, a trained Research Assistant (RA) will review each sampled medical chart to determine whether the patient experienced a TBI during the specified visit according to the CDC TBI definition. The RA will first review the selection criteria to confirm eligibility into the study. Approximately, 150 medical records from Emergency Department Patients, obtained from emergency medical records (EMR) will be abstracted to determine if they fit the TBI case definition: (1) any period of observed or self-

reported confusion, memory dysfunction, or loss of consciousness, (2) observed signs of neurological/neuropsychological dysfunction or (3) an injury to the head that resulted in amnesia, skull fracture, or intracranial lesion. It is estimated that this data abstraction will take 105 minutes per record, totaling 263 annual burden hours. Also, 50 Concussion Service Patient records will be obtained from a hospital concussion clinic. These records will be abstracted to determine if they fit the TBI case definition as well. It is estimated that this abstraction will take 105 minutes per record, totaling 88 annual burden hours. The total annualized burden hours per year are 351. The RA will be blinded to all ICD-9 CM codes while reviewing medical charts and entering data into the TBI Data extraction tool.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|------------------------------|--|--------------------|---------------------------------|------------------------------------|------------------------|
| Emergency Department Patient | Allscripts ED electronic medical record (EMR) system | 150 | 1 | 105/60 | 263 |
| Concussion Services Patient | Microsoft Access Patient List | 50 | 1 | 105/60 | 88 |
| | Total | | | | 351 |

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Kimberly S. Lane,
Deputy Director,
Office of Scientific Integrity,
Office of the Associate Director for
Science,
Office of the Director,
Centers for Disease Control and Prevention.

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